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10/071,174	02/07/2002	John C. Reed	087102 0272558	2991

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,174	REED ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-141* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-141* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 7/7/03 has been entered. Claims 1-141 are currently pending in the application and are addressed herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, 26-28, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1, for example.

Should the above Group be elected, further Group election of one of the following patently distinct subgroups is also required. (To be clear, this is not a species election, but a Group restriction wherein the following sub-groups are linked by the linking claims of Group I). The sub-groups are as follows:

A. Claims 24, 25, 42-45, 76 and 77 drawn to the isolated nucleic acid of Group I wherein the nucleic acid encodes a polypeptide classified in class 536, subclass 536, subclass 23.1.

B. Claims 24 and 73-75 drawn to the isolated nucleic acid of Group I wherein the nucleic acid encodes an antisense molecule, classified in class 536, subclass 24.5

II. Claim 29, drawn to a transgenic animal, classified in class 800, subclass 8.

Should the above Group be elected, further Group election of one of the following patently distinct subgroups is also required. (To be clear, this is not a species

election, but a Group restriction wherein the following sub-groups are linked by the linking claims of Group II). The sub-groups are as follows:

A. Claims 30-32, drawn to the transgenic animal of Group II wherein the transgenic animal expresses a polypeptide, classified in class 800, subclass 8.

B. Claims 30-32, drawn to the transgenic animal of Group II wherein the transgenic animal expresses an antisense molecule, classified in class 800, subclass 8.

III. Claims 33-41, drawn to a transgenic plant/seed, classified in class 800, subclass 295.

IV. Claims 46-63 and 70-72, drawn to an isolated polypeptide including a chimeric polypeptide, classified in class 530, subclass 300.

V. Claims 64-69 and 73-75, drawn to an antibody and kit comprising said antibody, classified in class 530, subclass 387.1.

VI. Claim 78, drawn to a method of detecting the presence of a target molecule using a nucleic acid as a probe, classified in class 435, subclass 6.

VII. Claim 78, drawn to a method of detecting the presence of a target molecule using an antibody, classified in class 530, subclass 412.

VIII. Claims 79-104, drawn to a method for modulating apoptosis in a cell comprising contacting the cell with a polypeptide, classified in class 514, subclass 2.

IX. Claims 79-104, drawn to a method for modulating apoptosis in a cell comprising contacting the cell with a nucleic acid, classified in class 514, subclass 44.

X. Claims 79-104, drawn to a method for modulating apoptosis in a cell comprising contacting the cell with an antibody, classified in class 424, subclass 130.1.

XI. Claims 90-104, drawn to a method of modulating apoptosis in a subject (i.e., treatment) using an antisense nucleic acid, classified in class 514, subclass 44.

XII. Claims 105-115, drawn to a method for identifying a modulator that modulates expression of a polypeptide, classified in class 435, subclass 6.

Should any of above Groups VIII-XII be elected further election of one (1) of the following patentably distinct sub-groups is also required. To be clear this is not a species election, but a group restriction. The subgroups are as indicated in claim 89 and 93:

a) Alzheimer's disease, b) Parkinson's disease, c) CJD, d) HD, e) MJD, f) SCA-1, g) SCA-2, h) SCA-6, i) DRPLA, j) Kennedy's disease, k) ischemia, l) stroke, and m) head trauma

XIII. Claims 116-119, drawn to a method for identifying a modulator that modulates the activity of a polypeptide, classified in class 435, subclass 6.

XIV. Claims 120-127, drawn to a method to identify molecules that bind to a polypeptide, classified in class 530, subclass 412.

XV. Claims 128-132, drawn to a method for detecting Bcl-B in a sample, classified in class 435, subclass 6.

XVI. Claims 133-141, drawn to a method to identify agents that modulate the binding of a polypeptide, classified in class 435, subclass 7.1.

Claims 1-23 and 26-28 link(s) the inventions of Groups IA and IB, and claims 89 and 93 link Inventions VIII-XII. Additionally claim 29 link(s) the inventions of Groups IIA and IIB. The restriction requirement between the linked inventions is subject to the nonallowance of the

linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V (including IA, IB, IIA and IIB) are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the products are unrelated because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. For instance polynucleotides, polypeptides, antibodies, transgenic animals and transgenic plants are chemically and structurally different and have different modes of operation and different functions and effects.

Inventions VI-XVI (including VIII-XII a-m) are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions the different methods are unrelated because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

Invention I (including IA and IB) is related to Inventions VI, IX and XI (including IX and XI a-m) as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (a nucleic acid) can be used in a materially different process, such as hybridization assays, template for PCR reaction, template for making encoded polypeptide either in vitro or in vivo, inhibiting expression of target nucleic acid sequences, and isolation of nucleic acid binding proteins.

Invention VI is related to Inventions VIII, XII-XIV and XVI (including XII a-m) as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (a polypeptide) can be used in materially different process such as: to make antibodies specific to the polypeptide, to identify molecules that bind the protein, to treat an animal having a disease.

Inventions V is related Inventions VII, X (including X a-m) and XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (an antibody) can be used in a materially different process such as: to isolate a specific polypeptide, to detect the presence of a specific polypeptide, to inhibit the activity of a specific polypeptide such as in treatment of a disease, etc.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each Group is distinct from the searches required for the other Groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

The species of claim 23 are: adenovirus, retrovirus, adeno-associated virus, lentivirus, reovirus, rotavirus, HSV, parvovirus, pappilloma virus, CMV.

The species of claims 32, 57, 84 are: cells of the heart, brain, lung, kidney, liver, pancreas, spleen, thymus, colon, muscle, leukocyte, small intestine, testis, prostate, ovary.

The species of claim 55 are: modulating apoptosis, homodimerization, heteromerization, binding to BCL-2, BCL-XL, BAX, forming a membrane channel, associating with a mitochondria, immunogenicity.

The species of claim 60 are: BH1, BH2, BH3, BH4 domains set forth in Fig. 1A.

The species of claim 94 are: sequence complimentary to Bcl-B sense strand, a sequence that forms triplex with Bcl-B, a ribozymes, a DNAzyme, or an RNAi molecule.

If Applicants elect a Group containing one of the above mentioned claims (23, 32, 57, 84, 55, 60) Applicant is required under 35 U.S.C. 121 to elect a **single** (1) disclosed species for **each** elected claim for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Robert Bedgood to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1635

DAVID T. NGUYEN
PRIMARY EXAMINER